

Notice of Allowability

Application No.

10/044,650

Examiner

Robert M. Kelly

Applicant(s)

GOINS ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/2/05.
2. ☒ The allowed claim(s) is/are 1, 3-5, 8-13, 15-19, 29-30, 33-34, and 37-38.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

PRELIMINARY NOTE

Applicant's amendment and response of 11/2/05 is entered prior to making the Examiner's Amendment, provided below.

Examiner Reassignment

Examiner Nguyen has been promoted to SPE of Art Unit 1633. This Application has been reassigned to Examiner Robert M. Kelly, of Art Unit 1633. All future correspondence should be so-addressed. The last paragraphs of this Action provide the Examiner's and SPE's information.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Krazsenek on 12/21/2005. During the interview, the Examiner indicated that claims 33 and 37 depended from cancelled claims 32 and 36, respectively. The Examiner suggested amending the claims to depend from claims 1 and 15, again, respectively. Mr. Krazsenek agreed to such amendment, and it was agreed that the Examiner would perform such amendment by Examiner's amendment, which would accompany the notice of allowance.

The application has been amended as follows:

IN THE CLAIMS:

1. Claim 33 has been amended as follows:
 33. The method of claim ~~32~~1, wherein the liposome comprises a size range of 50 to 300 nm.
2. Claim 37 has been amended as follows:
 37. The method of claim ~~36~~15, wherein the liposome comprises a size range of 50 to 300 nm.

The following is an examiner's statement of reasons for allowance:

The Examiner has reviewed the Application prosecution, and agrees with the previous Examiner's arguments, and further agrees that Applicant has overcome all bases of rejection. Furthermore, the Examiner finds no more issues with Applicant's claimed subject matter, and a further search indicates that the prior art, while teaching many aspects, does not teach the biotin-coated ligand, and further the fact that Applicant has found a surprising and unexpected result for the claimed subject matter: much higher uptake in the lymph node compared to other similar methods, as was previously stated (e.g., Official Action of 6/29/05, p. 11, paragraph 3). Furthermore, in light of Applicant's submission of 11/2/05 and co-submitted declaration by Dr. Beth A. Goins, it is clear that many routes of administration may be used and target many different lymph nodes without undue experimentation. Also, Applicant's amendments to

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liposomes, biotin, avidin, and cancellation of claims to sizes of 5 nm, overcome the other bases of rejection under enablement in the Official Action of 6/29/05. Still also, Applicant's cancellation of claims to messaging the injection site have been cancelled, thereby mooting the rejections based on written description in the Official Action of 6/29/05. Therefore, all bases of rejection have been withdrawn, and the claims are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 1, 3-5, 8-13, 15-19, 29-30, 33-34, and 37-38 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

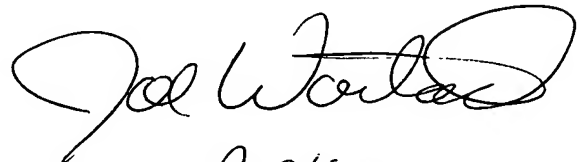
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JOSEPH WOTACH, PH.D.
PRIMARY EXAMINER


AU 1633